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10/817,500	04/02/2004	Frank Jao	ARC 2258 C1	3152

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SHEIKH, HUMERA N	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,500	JAO ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 4-11* is/are pending in the application.

4a) Of the above claim(s) *11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 4-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/24/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response and Amendment after Non-Final Office Action and Applicant's Arguments/Remarks, both filed 05/29/07 and the Information Disclosure Statement (IDS) filed 05/24/07 is acknowledged.

Applicant has overcome the 112, 2nd paragraph rejection for claim 5 (lack of antecedent basis for the term "material"), by virtue of the amendment to the claim.

Claims 1 and 4-11 are pending in this action. Claims 1, 4 and 5 have been amended. Claims 2 and 3 have been cancelled. Claim 11 was previously withdrawn (non-elected subject matter). Claims 1 and 4-10 remain rejected.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 and 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Theeuwes *et al.* (U.S. Patent No. 4,058,122).

The instant invention is drawn to a dosage form for delivering an antiepileptic drug to a gastrointestinal tract, comprising: a compartment containing a drug formulation layer, the drug

formulation layer comprising an antiepileptic drug; a semipermeable wall surrounding the compartment, the semipermeable wall having a passageway that allows communication between the compartment and an exterior of the dosage form; an internal lamina formed on an inner surface of the semipermeable wall, the internal lamina being substantially soluble in water, wherein the internal lamina comprises one or more water-soluble polymers, and he one or more water-soluble polymers are present in the internal lamina in an amount of at least 80% by weight; wherein the internal lamina in a hydrated state forms a gelatinous layer that lubricates the semipermeable wall, thereby substantially preventing crack formation in the semipermeable wall while the dosage form is dispensing the drug.

Theeuwes *et al.* ('122) teach an osmotic system for delivering an agent. The system comprises a wall surrounding a compartment and has a passageway for delivering agent from the compartment. The wall is formed of laminae comprising a lamina consisting of a multiplicity of materials in laminar arrangement with a lamina consisting of a material or of a multiplicity of materials to provide a laminated wall that is permeable to agents and maintains its integrity during delivery of the agent. The compartment contains an agent that is soluble in an external fluid and exhibits an osmotic pressure gradient across the wall against the fluid or the agent has limited solubility in the fluid and is mixed with an osmotically effective compound soluble in the fluid and exhibits an osmotic pressure gradient across the wall against the fluid. Agent is released from the system by fluid being imbibed through the wall into the compartment at a rate controlled by the permeability of the wall and the osmotic pressure gradient across the wall producing a solution-containing agent or a solution of compound-containing agent (see

Abstract). The laminated wall is formed of at least one semipermeable lamina; (col. 1, line 14 - col. 3, line 10).

The drawings demonstrate various osmotic systems of the invention. Figs. 1A and 1B, for instance, demonstrate an osmotic system 10 in the form of an oral, osmotic therapeutic system that is comprised of a body 11 having a semipermeable laminated wall 12 that surrounds a compartment 1, seen in Fig. 1B in opened section with a portion of wall 12 removed at 14. System 10 has a passageway 15 in wall 12 that extends through 12 and communicates with compartment 13 and the exterior of system 10. Compartment 13 is a means for containing a beneficial agent 16 that is soluble in an external fluid and exhibits an osmotic pressure gradient across wall 12 against an external fluid or compartment 13 optionally contains a mixture of agents 16 with at least one agent exhibiting an osmotic pressure gradient (col. 3, line 54 – col. 4, line 14).

In Fig. 1C, wall 12 comprises a lamina consisting of an exterior semipermeable lamina 19 and an interior semipermeable lamina 20.

In one embodiment, lamina 19 is a composite comprising at least two materials blended to form a lamina that is (a) permeable to the passage of an external fluid, (b) maintains its physical and chemical integrity in the environment of use, and is more particularly substantially non-erodible and inert in the environment, c) provides mechanical support for other laminae comprising wall 12 and d) optionally is impermeable to compounds present in the environment of use (col. 4, lines 15-31).

In one embodiment, lamina 20 is a composite comprising at least two materials blended to form a semipermeable lamina that is (e) permeable to the passage of an external fluid, (f)

substantially impermeable to passage of the agent and compound present in the compartment, (g) maintains its physical and chemical integrity in the presence of agent and is more particularly substantially non-erodible and inert in the presence of agent, h) provides mechanical support for other laminae forming wall 12 and i) is substantially impermeable to compounds present in the environment of use (col. 4, lines 32-61).

Materials suitable for forming laminae consisting of a single material are generically polymeric materials. The polymeric materials are homopolymers and copolymers and they include materials known as semipermeable, osmosis and reverse osmosis materials (col. 7, line 22 – col. 8, line 6).

Representative materials of the wall include polymeric cellulose esters and copolymeric cellulose esters such as cellulose acylate, cellulose diacylate and cellulose triacylate (mono, di and tricellulose acylates) (col. 8, lines 7-10).

The semipermeable laminae forming materials also include cellulose ethers such as alkylcellulose, methylcellulose, ethylcellulose, ethylmethylcellulose, hydroxypropylcellulose, hydroxypropylmethylcellulose and the like (col. 10, lines 4-19).

Other semipermeable materials useful for forming laminae include copolymers of alkylene oxides and alkyl glycidyl ethers (col. 10, lines 20-47).

Active drugs for use in the invention include drugs that act on the central nervous system such as hypnotics and sedatives, including pentobarbital sodium, phenobarbital, secobarbital, thiopental and mixtures thereof (col. 20, lines 7-12).

It is noted that while Theeuwes does not explicitly teach the instantly claimed percentage of water-soluble polymers (of at least 80% by weight), generally, differences in concentration

will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Applicants have not demonstrated any superior or unexpected results, which accrue from the claimed weight amount of water soluble polymer. The prior art recognizes and teaches a structurally similar dosage formulation comprising similar ingredients, used for the same field of endeavor as that of the Applicants. No patentable distinction has been observed, which accrues from the instant amounts claimed since effective results are obtained using the dosage systems of Theeuwes.

Given the teachings of Theeuwes discussed above, the instant invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Pertinent Art

Prior Art made of record, not relied upon and cited of interest:

- **Edgren *et al.*** (U.S. Pat. No. 5,190,763) (03/1993):

  Edgren *et al.* teach an osmotic dosage device comprising a wall (12) that surrounds and defines an internal compartment (15). The wall (12) comprises at least one exit means (13) that connects compartment (15) with the exterior of dosage form (10). Dosage form (10) can comprise more than one exit means.

Representative materials for the semipermable wall include cellulose acylate, cellulose diacylate, cellulose triacylate (see col. 3, line 42 – col. 4, line 17).

- **Khan *et al.*** (U.S. Pat. No. 5,656,296) (08/1997):

  Khan *et al.* teach dual control sustained release drug delivery systems and methods for preparing, whereby the system comprises a core and a porous coating layer over the core (Abstract). Suitable drugs taught include antiepileptics, such as sodium phenytoin (col. 3, line 44).

Response to Arguments

Applicant's arguments filed 05/29/07 have been fully considered and were found partially persuasive.

Rejection under 35 U.S.C. §112, 2nd paragraph:

Applicant argued, "Claim 5 was rejected under 35 USC 112, because the term "semipermeable material" lacked sufficient antecedent basis. The phrase "semipermeable material is" has been replaced with the phrase "semipermeable wall includes a member".

Applicant's arguments were found persuasive by virtue of the amendment to claim 5, replacing "semipermable material is" with "semipermeable wall includes a member". Accordingly, the 112, 2nd paragraph rejection of claim 5 has been withdrawn.

Rejection under 35 U.S.C. §103(a) over Theeuwes et al. (US 4,058,122):

Applicant argued, "Theeuwes et al disclose an osmotic system comprising a semipermeable laminated wall (12) surrounding a compartment (13). The semipermeable laminated wall includes an exterior semipermeable lamina (19) that maintains its physical and chemical integrity and is more particularly substantially non-erodible in an environment of use and an interior semipermeable lamina (20) that

maintains its physical and chemical integrity and is more particularly substantially non-erodible in the environment (col. 4, lines 15-61). The interior semipermeable lamina (20) of Theeuwes et al cannot meet the following limitation of claim 1: "an internal lamina formed on an inner surface of the semipermeable wall, the internal lamina being substantially soluble in water, wherein the internal lamina comprises one or more water-soluble polymers, and the one or more water-soluble polymers are present in the internal lamina in an amount of at least 80% by weight." In the claimed invention, in an environment of use, the internal lamina forms a gelatinous layer as it imbibes fluid. This gelatinous layer thickens with further hydration so that the internal lamina acts as a lubricant for the semipermeable wall, thereby preventing crack formation in the semipermeable wall as the semipermeable wall is pushed out due to hydrostatic pressure in the compartment.

Although Theeuwes et al disclose that the semipermeable forming materials in the semipermeable laminated wall (12) could include water-soluble materials such as hydroxypropylcellulose and hydroxypropylmethylcellulose, it is obvious that the interior semipermeable lamina (20) cannot include a significant amount of water-soluble materials which would render the interior semipermeable lamina substantially soluble in water if the interior semipermeable lamina is to maintain its physical and chemical integrity and be more particularly substantially non-erodible in the environment of use. In fact, Theeuwes et al teach away from the invention as claimed in disclosing that the interior semipermeable lamina is required to maintain its physical and chemical integrity and be more particularly substantially non-erodible in the environment of use. Theeuwes et al also teach that the interior semipermeable wall (20) is preferably more hydrophobic, has a higher degree of agent and compound rejection, and has decreased permeability to an external fluid in comparison to the exterior semipermeable wall (col. 4, lines 45-52)."

Applicant's arguments have been considered, but were not persuasive since the Theeuwes reference does use polymers that are recognized as being water-soluble. The percentage of water-soluble polymers claimed by Applicant of "at least 80% by weight", while not disclosed by Theeuwes, does not provide for a "patentable" distinction over the osmotic structures of the cited reference. The lamina of the reference has water-soluble polymers, albeit, it is the intent of the reference that the tablet maintain its structure until the drug is delivered. Eventually the compartment breaks down and degrades. Moreover, as noted above, generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller,* 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). In this instance, Applicants have not demonstrated any superior or unexpected results, which accrue from the claimed weight amount of water-soluble polymer. The determination of suitable amounts can be carried out through routine experimentation to obtain optimal results, as

these are variable parameters attainable within the art. Thus, Applicant's arguments were not found persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

This application contains claim 11 drawn to an invention nonelected with traverse in the reply filed on 12/30/06. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

HUMERA N SHEIKH
PRIMARY EXAMINER

Primary Examiner

Art Unit 1615

August 03, 2007

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